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510(k) Summary

Submitter:	Edwards Lifesciences® LLC
Contact Person:	Spencer Walker, Regulatory Affairs Associate II 12050 Lone Peak Pkwy Draper, UT 84020 (801) 565-6100
Date Prepared:	September 13, 2011
Trade Name:	Edwards Lifesciences EndoClamp Aortic Catheter
Classification Name:	Vascular Clamp 21 CFR Part 870.4450, Product Code DXC, Class II
Predicate Device:	K974175: HeartPort Endoaortic Clamp Catheter

Device Description:

The EndoClamp aortic catheter is a 10.5 Fr, wire-reinforced, three-lumen catheter with an elastomeric balloon near its tip for occluding the ascending aorta in order to partition the aortic root from arterial circulation. The balloon expands to occlude a range of aorta sizes. The large central lumen of the catheter serves two functions: delivery of cardioplegic solution to the aortic root and venting of fluid and air from the aortic root. The two remaining lumens serve as conduits for balloon inflation and aortic root pressure monitoring. The shaft is marked to indicate the insertion depth. A Clamp-Lock™ device, provided on the shaft, allows the catheter to be locked in position. A color-coded 3-way stopcock is attached to each lumen for fluid injection, balloon inflation and aortic root pressure monitoring. A rotating hemostasis valve (RHV) is attached to the large central lumen for guidewire insertion on the 100 cm catheter. The Y-connector with three tubing clamps, which enables alternation between cardioplegic solution delivery and aortic root venting, is attached to the central lumen. A vacuum relief valve is included for aortic root venting. Pressure monitoring lines are attached to the balloon inflation lumen and to the aortic root pressure monitoring lumen. Two color-coded 35 mL syringes are included for contrast injection and balloon inflation. A guidewire is provided with the 100 cm EndoClamp catheter. The devices are provided sterile and non-pyrogenic, and intended for single use only.

Intended Use:

The EndoClamp Aortic Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The EndoClamp Aortic Catheter occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

Comparative Analysis:

It has been demonstrated that the EndoClamp Aortic Catheter is comparable to the predicate device in intended use and other labeling, fundamental scientific technology, material types, principles of operation and functional performance evaluations. The 'Y'-connector material formulation change has been fully assessed within the Edwards Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm safety and efficacy.

Functional/Safety Testing:

The functional data indicate that the EndoClamp Aortic Catheter performs in a substantially equivalent manner when compared with the predicate device. The following functional tests were performed. All data met pre-established acceptance criteria.

- Biocompatibility – Per ISO 10993-1 for External communicating device, indirect blood path, duration ≤24 hours.
- 'Y'-connector Pull Testing - Pull test of the 'Y'-connector and bonded tubing for bond strength.
- 'Y'-connector Burst/ Leak Testing – Burst/Leak to test the 'Y'-connector and bonded tubing for device leakage.

Conclusion:

The EndoClamp Aortic Catheter is substantially equivalent to the predicate device. The subject change to material formulation has no negative impact on the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 14 2011

Edwards Lifesciences, LLC
c/o Mr. Spencer Walker
Regulatory Affairs Associate II
12050 Lone Peak Parkway
Draper, UT 84020

Re: K112694
Trade/Device Name: EndoClamp Aortic Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 14, 2011
Received: September 15, 2011

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K112694

Device Name: Edwards Lifesciences EndoClamp Aortic Catheter

The EndoClamp Aortic Catheter is indicated for use in patients undergoing cardiopulmonary bypass. The EndoClamp Aortic Catheter occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

Prescription Use x OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112694